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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/981,824	09/18/98	ENDL	J P564-7029

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EXAMINER	
DIBRINO,M	
ART UNIT	**PAPER NUMBER**
1644	9

DATE MAILED: 03/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/981,824	Endl et al
Examiner	**Group Art Unit**
Marianne DiBrino	1644

☒ Responsive to communication(s) filed on *Jan 18, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-3 and 5-52* is/are pending in the applicat

Of the above, claim(s) *6-17 and 21-52* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-3, 5, and 18-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *1*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicants are required to amend the specification to list the appropriate SEQ ID NOS for sequences disclosed in the specification (for example, in the Figure legends.)

2. Applicant's amendment filed 1/18/00 is acknowledged and has been entered.

Claim 4 has been canceled. Claims 1-3 and 5-52 are pending.

3. Applicant's election of the Invention of Group I, claims 1-3, 5, 6 and 18-20, and species of peptide of SEQ ID NO: 7 recited in claim 1 (part (g)) with traverse in Paper No. 5 is acknowledged. The traversal is on the assertion that claim 1 does not read on the intact protein taught by Tobin in WO 95/07992.

Applicant's arguments were considered, but are not deemed persuasive. Because of the open transitional phrase "comprising" in instant claim 1, the partial GAD peptide sequences of the instant claim 1 read on the intact GAD protein.

The requirement is still deemed proper and is therefore made FINAL.

The invention being examined in this application is a peptide and pharmaceutical composition thereof, comprising the species of peptide listed in claim 1(g). Claims 1-3, 5 and 18-20 are readable on the elected species.

Claims 6 (non-elected species of Group I), 7-17 and 21-51 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

4. The reference "AH" crossed out in the Form 1449 filed 1/14/98 has not been considered because a translation has not been provided.

5. The Abstract of the Disclosure is objected to because:

a. The form and legal phraseology often used in patent claims, such as "therewith" should be avoided.
b. The first letter of the first sentence should be capitalized and the "t" in "t cell" should also be capitalized.

Correction is required. See MPEP 608.01(b).

6. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3, 5 and 18-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1 is indefinite in the recitation of " "(g) the amino acid sequence **(IV) (SEQ ID NO: 4)** F-F-R-M-V-I-S-N-P-A-A-T-H-Q-D-I-D-F-L-I" because F-F-R-M-V-I-S-N-P-A-A-T-H-Q-D-I-D-F-L-I is not SEQ ID NO: 4. It appears that F-F-R-M-V-I-S-N-P-A-A-T-H-Q-D-I-D-F-L-I is SEQ ID NO: 7.

b. Claim 1 is indefinite in the recitation of the roman numerals in parts (a) - (g) because it is not clear what the roman numerals stand for. The peptide sequences appearing in the instant claim are identified by SEQ ID NO.

9. Claim 5 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from any other multiple dependent claim. See MPEP § 608.01(n).

10. For the purpose of prior art rejections, the filing date of the instant claims 1-5 and 18-20, is deemed to be the filing date of the PCT/EP96/03093, i.e.7/15/96, as the foreign priority document GB 195 25 784.7 does not disclose the elected species.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-3, 5 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Tobin et al (WO 92/05446).

Tobin et al teach a peptide/derivative comprising F-F-R-M-V-I-S-N-P-A-A-T-H-Q-D-I-D-F-L-I (SEQ ID NO: 7) especially figure 4, amino acid residues 556-575. Tobin et al teaches a pharmaceutical composition comprising said peptide (especially page 12, lines 13-15). Tobin et al further teaches that said peptide can be labeled with a marker (especially page 12, lines 15-16 and page 10, lines 2-3) . Instant claim 19 is included because Tobin et al teach that preparations for parenteral administration include oils such as fixed oils and vegetable oils (especially page 14, lines 21-27) which can act as adjuvants, i.e., accessory-stimulating components. Because of the open transitional phrase "comprising" in instant claim 1, the partial GAD peptide sequences of the instant claim 1 read on the intact GAD protein.

The reference teachings anticipate the claimed invention.

14. Claims 1-3 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Baekkeskov et al (WO 94/12529, IDS reference "AM").

Baekkeskov et al teach a peptide/derivative comprising F-F-R-M-V-I-S-N-P-A-A-T-H-Q-D-I-D-F-L-I (SEQ ID NO: 7) especially figure 1, amino acid residues 556-575, upper sequence. Baekkeskov et al teach a pharmaceutical composition comprising said peptide (especially pages 35-37). Instant claim 19 is included because Baekkeskov et al teach that pharmaceutical preparations contain adjuvants (especially page 35, line 33), i.e., accessory-stimulating components. Because of the open transitional phrase "comprising" in instant claim 1, the partial GAD peptide sequences of the instant claim 1 read on the intact GAD protein.
The reference teachings anticipate the claimed invention.

15. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Tobin et al (EP 0519469A1, IDS reference "AG").

Tobin et al teach a peptide/derivative comprising F-F-R-M-V-I-S-N-P-A-A-T-H-Q-D-I-D-F-L-

I (SEQ ID NO: 7) especially figure 4, amino acid residues 556-575.

The reference teachings anticipate the claimed invention.

16. Claims 1-3, 5 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Tobin et al (WO 95/07992, IDS reference "AN").

Tobin et al teach a peptide/derivative comprising F-F-R-M-V-I-S-N-P-A-A-T-H-Q-D-I-D-F-L-I (SEQ ID NO: 7) especially figure 4, amino acid residues 556-575. Tobin et al teaches a pharmaceutical composition comprising said peptide (especially page 14, lines 34-37 and page 17, lines 25-27). Tobin et al further teaches that said peptide can be labeled with a marker (especially page 14, lines 12-14) . Instant claim 19 is included because Tobin et al teach that preparations for parenteral administration include oils such as fixed oils and vegetable oils (especially page 27, lines 25-35) which can act as adjuvants, i.e., accessory-stimulating components.

The reference teachings anticipate the claimed invention.

17. Claims 1-3, 5 and 18-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tobin et al (WO 92/05446) in view of Burke et al (U.S. Patent No. 5,750,114).

Tobin et al teach a peptide/derivative comprising F-F-R-M-V-I-S-N-P-A-A-T-H-Q-D-I-D-F-L-I (SEQ ID NO: 7) especially figure 4, amino acid residues 556-575. Tobin et al teaches a pharmaceutical composition for immunotherapy of an autoimmune disease comprising said peptide (especially page 12, lines 13-15 and claims 23 and 28). Tobin et al further teaches that said peptide can be labeled with a marker (especially page 12, lines 15-16 and page 10, lines 2-3) . Instant claim 19 is included because Tobin et al teach that preparations for parenteral administration include oils such as fixed oils and vegetable oils (especially page 14, lines 21-27) which can act as adjuvants, i.e., accessory-stimulating components. Because of the open transitional phrase "comprising" in instant claim 1, the partial GAD peptide sequences of the instant claim 1 read on the intact GAD protein.

Tobin does not teach said composition wherein the accessory-stimulating component is a cytokine.
Burke et al teach an HSV polypeptide vaccine which further comprises immunomodulating cytokines such as IL-2 and a pharmaceutically acceptable carrier (especially column 4, lines 7-38).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include a cytokine such as that found in the pharmaceutical composition taught by Burke et al.

with the peptide of Tobin.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this because it was well known in the art at the time the invention was made to help elicit an immune response to an administered peptide antigen using a cytokine, and as exemplified by the teaching of Burke et al for the composition comprising a peptide, IL-2 and a pharmaceutically acceptable carrier.

18. No claim is allowed.

19. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware of in the in the specification.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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